510(k) Summary

NOV 21 2008

Pou Yu Biotechnology Co., Ltd
TDS Abutment

ADMINISTRATIVE INFORMATION

Manufacturer Name:	Pou Yu Biotechnology Co., Ltd. No. 6 Fugong Rd. Fusing Township Changhua County 506, Taiwan Telephone: +886-(0)4 768 5660 x5122 Fax: +886-(0)4 768 9032
Official Contact:	Daniel Tsao
Representative/Consultant:	Linda K. Schulz Floyd G. Larson PaxMed International, LLC 11234 El Camino Real, Suite 200 San Diego, CA 92130 Telephone: +1 (858) 792-1235 Fax: +1 (858) 792-1236 email: lschulz@paxmed.com flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	TDS Abutment
Common Name:	Dental implant abutment
Classification Regulations:	Endosseous dental implant abutment Class II, 21 CFR 872.3630
Product Code:	NHA
Classification Panel:	Dental Products Panel
Reviewing Branch:	Dental Devices Branch

INTENDED USE

TDS Abutment is intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.

DEVICE DESCRIPTION

TDS Abutments are custom titanium or ceramic abutments designed to be used in conjunction with specific dental implants utilizing the screw provided by the implant manufacturer. In combination with the implant, the abutments support single or multi-unit cement-retained restorations in the maxillary and/or mandibular arch. TDS Abutments made of titanium are available for Nobel Biocare Replace® RP (Ø 4.3 mm) implants. TDS Abutments made of ceramic are available for Nobel Biocare Replace® WP (Ø 5.0 mm) implants and BioHorizons Internal 4.0 (Ø 4.5 mm platform) implants.

EQUIVALENCE TO MARKETED DEVICE

Pou Yu Biotechnology Co. Ltd demonstrated that, for the purposes of FDA's regulation of medical devices, TDS Abutment is substantially equivalent in indications and design principles to predicate devices, each of which has been determined by FDA to be substantially equivalent to preamendment devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Pou Yu Biotechnology Company, Limited
C/o Ms. Linda K. Schulz
Regulatory Affairs
PaxMed International, LLC
11234 EL Camino Real, Suite 200
San Diego, California 92130

NOV 21 2008

Re: K081460
Trade/Device Name: TDS Abutment
Regulation Number: 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: November 19, 2008
Received: November 20, 2008

Dear Ms. Schulz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Chiu S. Lin, Ph. D
Division Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081460

Device Name: TDS Abutment

Indications for Use:

TDS Abutment is intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K081460